REMARKS

The office action of December 16, 2009 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 7 through 12 and 19 through 24 remain in this case, claims 7, 12, and 19 being amended by the present response. No new matter was introduced by these amendments. Specifically, claims 7, 12, and 19 were re-worded to positively include means and a step of calculating a transfer function and an impulse response.

The numbered paragraphs below correspond to the numbered paragraphs in the Office Action.

Rejections under 35 U.S.C. §112

2. Claims 7-12 and 19-24 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states that the claims are indefinite because it is unclear "whether Applicant is positively reciting that the impulse response must be calculated by performing steps corresponding to the claimed functional limitations" [page 3, lines 2-3, present office action dated December 16, 2009].

Although Applicant respectfully disagrees with the rejection, to further prosecution claims 7, 12, and 19 have been amended to positively recited means for calculating and a step of calculating "a transfer function by computing a Fourier transform of normal-activity biosignals from normal biological activities" and "an impulse response by computing an inverse Fourier transform of the transfer function".

Applicant believes that these amendments have fully addressed the Examiner's rejections, and the claims are now in condition for allowance. Reconsideration and withdrawal of the rejection of claims 7-12 and 19-24 are respectfully requested.

Rejection under 35 U.S.C. §103

5. Claims 7 through 12 and 19 through 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shalev (2006/0089678) in view of Constant (4,006,351). Applicant respectfully disagrees with the rejection.

Amended independent claims 7 and 12 each include, in part, "a calculating means which receives the input biosignals, calculates a transfer function by computing a Fourier transform of normal-activity biosignals from normal biological activities, calculates an impulse response by computing an inverse Fourier transform of the transfer function, calculates a plurality of stimulation signals for stimulation of an organism using a convolution integral between the input biosignals and [an] impulse response, and outputs the stimulation signals for stimulation of the organism" and "an organism stimulating means which receives the stimulation signals … and stimulates the organism based on the stimulation signals" (emphasis added).

Amended independent claim 19 includes, in part, the steps of "calculating a transfer function by computing a Fourier transform of normal-activity biosignals from normal biological activities and calculating at least one impulse response by computing an inverse Fourier transform of the transfer function", "calculating a plurality of stimulation signals for stimulation of an organism using a convolution integral between the impulse response and the input biosignals", and "outputting the stimulation signals for stimulation of the organism only if the input biosignals are determined to be caused by abnormal biological activities".

Shalev teaches that there are two types (Type I and Type II) of baroreceptors (see paragraphs [0013] and [0016]). The type I baroreceptors are involved in the dynamic (non-tonic) regulation of blood pressure (see paragraph [0015]). On the other hand, Type II baroreceptors are involved in the tonic regulation of blood pressure (see paragraph [0018]).

Shalev teaches only a simple instantaneous function in paragraph [0062], where a nerve stimulating condition is decided based on the blood pressure value only at the present time, not taking the previous blood pressure values (history of pressure values or time series of blood pressure) into consideration. This instantaneous response curve/function is known to be constant in type II baroreceptors but to be shifted from moment to moment in type I baroreceptors. The

latter phenomenon is known as "resetting". Due to the resetting phenomenon, the instantaneous function taught by Shalev cannot be used for properly regulating the type I baroreceptors or for regulating the dynamic (non-tonic) blood pressure (see paragraph [0036]).

The resetting phenomenon occurring in type I baroreceptors can be recognized in that the instantaneous function for type I baroreceptors is changeable. However, the problem may be solved by the systems of claims 7 and 12 and the method of claim 19 by considering the previous blood pressure values and by calculating a convolution integral between the impulse response and the blood pressure values previously obtained. In other words, the impulse response of claims 7, 12, and 19 may be used to overcome the resetting phenomenon. In claims 7, 12 and 19, the impulse response is used to include the effect of not only the present conditions but also the past values, as shown in Equation 2 from the present specification [$HR(t) = \sum_{\tau=1}^{N} h(\tau) \cdot SNA(t-\tau)$].

In Example 6 from the present specification, sympathetic nerve activity (STM) is determined by calculating the convolution integral between the impulse response (expressing biological dynamic baroreflex control) and the blood pressure. The estimated sympathetic nerve activity was applied, and its effectiveness (functional recovery from impaired blood pressure regulation) was evaluated by the amelioration of sudden hypotension soon after a passive 90-degree head-up tilt test in rats. The results proved that the systems of claims 7 and 12 and the method of claim 19 enabled dynamic (non-tonic) blood pressure regulation in rats. Therefore, the systems and method in claims 7, 12, and 19 produce a remarkably better result than the teachings of Shalev.

As the Examiner acknowledges, Shalev does not teach or suggest stimulation signals that are calculated from a convolution integral between an impulse response previously calculated and input biosignals. Since Shalev does not teach or suggest the stimulation signals, as defined in claims 7 and 12, Shalev also can not teach or suggest receiving those stimulation signals, and stimulating the organism based on the stimulation signals.

Regarding claims 7, 12, and 19, Constant does not provide what Shalev lacks. Constant teaches calculation of an output signal from a convolution integral between a previously-

obtained impulse response and an input signal to provide the predictable result of a better measurement of time delay and frequency in a noisy environment.

Constant does not teach or suggest biological responsiveness or the use of an impulse response as a measure of biological responsiveness that the systems and method of claims 7, 12, and 19 regulate. Constant does not teach input biosignals or using input biosignals as part of a convolution integral because Constant does not teach or suggest any type of biological system in which to use its teachings. Instead, Constant discusses using these measurements and calculations in radar, sonar, and communication applications, or in communication lines or amplifiers. "Impulse response" in Constant refers to a response in a linear time-invariant system. The impulse response in Constant is based on the assumption that the relationship between the input signal and the output signal is linear and time-invariant. Because of the complexities described below, a combination of Shalev and Constant would not produce any of the systems or method of claims 7, 12, and 19.

Although the impulse response of claims 7, 12, and 19 is superior to a simple instantaneous function to represent biological responsiveness, it is only an approximation as a linear time-invariant system. In other words, this impulse response is based on the assumption that the relationship between the input signal and the output signal is linear and time-invariant.

Even after using an impulse response and taking previous input values into consideration, many of the indications of biological responsiveness are, in fact, non-linear and variable with time. This is because complex factors (including, but not limited to, hormone levels, body temperature, and oxygen concentration) other than the input signals and output signals may influence the response. In other words, the output signal obtained by the impulse response is only an estimated value and varies with time and condition. Considering these complexities, it would require more than ordinary skill in the art to apply the teaching of Constant to Shalev to get an appropriate impulse response for a particular organism of interest.

For these reasons, even though Constant teaches regulation using an "impulse response", a mere combination of Constant and Shalev would not produce the system or method of claims 7, 12, and 19, and the impulse response of Constant would not be applied to an organism by someone skilled in the art because of the uncertainties. Biological responsiveness, expressed as a

linear impulse response, cannot be similarly applied to different organs of the organism because a linear impulse response would not work as an approximation in all organs. For instance, whether an estimated value of the obtained impulse response can be effectively used for controlling the organism depends on the organs, since the nonlinear nature and the other elements also have influence on the output calculated by the impulse response at various levels.

Those skilled in the art would not use Constant's impulse response or calculations in a system that includes biological responsiveness. In addition, since Constant's teachings are necessitated by a linear system and Shalev teaches a biological system, which is nonlinear, no one skilled in the art would modify Shalev's teachings with the teachings from Constant.

The systems and method of claims 7, 12, and 19 are characterized in that a signal for stimulation is output by a convolution integral between the impulse response (biological responsiveness) from normal biological activities and input biosignals obtained from a complex organism. As shown in examples in the application, control of the organism is possible with the systems of claims 7 and 12 and the method of claim 19. This control would not be possible using the teachings of Shalev and Constant, alone or in combination.

Since claims 7, 12, and 19 include multiple elements and steps not taught or suggested by Shalev or Constant, alone or in combination, claims 7, 12, and 19 are not obvious over Shalev in view of Constant. Claims 8-11 and 20-24, being dependent and further limiting independent claims 7 and 19, respectively, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicant's agent would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

Respectfully Submitted:
-- Japan and Fujikin Incorporated --

By: /KLH #57457/
-- Kraig Haverstick, Reg. No. 57,457 --
Agent for Applicant

BROWN & MICHAELS, P.C.
400 M&T Bank Building - 118 N. Tioga St.
Ithaca, NY 14850
(607) 256-2000 • (607) 256-3628 (fax)
e-mail: docket@bpmlegal.com
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